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10/519,364	01/18/2006	Ingela Petersson	0104-0496PUS1	3037
2292 7590 02/19/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
LEWIS, RALPH A				
ART UNIT		PAPER NUMBER		
3732				
NOTIFICATION DATE		DELIVERY MODE		
02/19/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

## Application No.

10/519,364

## Applicant(s)

PETERSSON ET AL.

## Examiner

Ralph A. Lewis

## Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 28-31 and 33-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 28-31 and 33-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **Objection to the Claims**

Claims 1 and 23-36 are objected to under 37 CFR 1.75(i) which requires each step of the claimed invention to be separated by a line indentation.

### **Rejections based on 35 U.S.C. 112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 23-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 1 indicates that a method for treating an implant surface is being claimed, yet the body of the claim fails to provide for a reasonably clear organized set of steps for accomplishing the claimed method. Moreover, from the manner in which claim 1 is drafted, it is unclear if the HF concentration, room temperature and etching period are positively required elements of the "providing microroughness" step.

### **Rejections based on Prior Art**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 28-31 and 33-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellingsen et al (WO 95/17217), optionally in view of Steinemann et al (US 5,456,723) and Haruyuki et al (JP-3146679).

Ellingsen et al disclose a method of treating titanium (page 5, line 24) dental (page 1, line 26) implants wherein in a preferred embodiment the titanium implants are exposed to hydrofluoric acid (HF) in a concentration from .1% to 2% at room temperature for up to a period of 3 minutes (180 seconds)(page 6, lines 20 - 24). Ellingsten et al also suggest, an HF concentration of "especially" in a range of 0.2%- to 0.5%, (note page 5, lines 27-31) and a broader time range of "any suitable length of time . . . such as 10 seconds to 6 hours" (page 6, lines 1-5). Ellingsten et al disclose that their method improves the rate of bone tissue attachment and strength or bonding (page 7, lines 12-15). Ellingsten et al, desiring not to be bound by theory attribute the improved osteointegration "at least in part, to fluoride being retained on the surface of the implant" (page 7, lines 17-19). Applicant's disclosure at page 15, lines 8-28, indicates that exposing titanium implants to HF inherently meets the claimed method step of "providing fluorine/fluoride on a surface of the implant.

Ellingsten et al do not discuss the presence or absence of micropores. They do however state that "[p]referably no significant etching of the implant surface occurs with the present treatment. Most preferably, there is substantially no etching of the implant surface." (page 8, lines 1-3). Applicant argues that such language teaches against any etching at all. The examiner is of the position, however, that such language more reasonably suggest to the ordinarily skilled artisan that while no significant macro-etching is occurring that some micro-etching does (or may) occur. Claim 1, requires less than 1  $\mu\text{m}$  and less than .5 $\mu\text{m}$  depth with no lower limits. Such claim limitations seemingly suggests that even insignificant nano-etching in Ellingsten et al would meet the size requirements. In responding to the rejection based on Ellingsten et al, applicant focuses on Figure 2 wherein an implant was treated with .2% HF for 30 seconds and argues that no etching has occurred. The examiner notes that Figure 3 is a higher magnification of the same surface and illustrates that some minor etching has occurred (as compared with untreated surface Figure 6). Moreover, Ellingsten et al disclose in Figure 4 a surface treated with .2% HF for 90 seconds which shows micro-etching – note particularly page 15, lines 15-28. A more reasonable interpretation is that Ellingsten et al disclose micro-etching, but characterizes such minor etching as not being "significant" or as "substantially no etching."

As to the claimed "etching period," claim 1 indicates that the "etching period" begins with the "formation of the first bubble of  $\text{H}_2$  (g) at the implant surface" (note also page 18, lines 3-21). Applicant does not disclose how long the implants are exposed to the HF acid solution before the "etching period" begins. In the remarks of 10/13/2009

applicant indicates that the length of time preceding the etching depends on the natural oxide layer and geometry of the implant, but applicant gives no indication as to how long that may be, no indication as to how long it was in their examples and indicates that the time preceding the etching is "not relevant." Ellingsten et al indicate that the treated implants are removed from sterile packaging and placed in the HF treatment bath (page 10, lines 11-15) which would appear to suggest that Ellingsten et al uses implants having a minimal natural oxide layer, consequently the chemical reaction between the titanium and HF would occur relatively quickly, a byproduct of which is  $H_2$  (g). Moreover, the examiner notes that the "formation of the first bubble" test seems fairly subjective depending on the size of the  $H_2$  (g) bubble. The examiner is of the position that the Ellingsten et al implants from sterile packaging would have very little natural oxidation and would begin forming  $H_2$  (g) bubbles almost immediately as the HF reacted with the titanium.

Applicant argues that the ordinarily skilled artisan would immediately remove the Ellingsten et al titanium implants from the HF if bubbles occurred because Ellingsten et al desires no etching. The examiner disagrees, Ellingsten et al specifically indicates that the implants be left in the HF solution for 30 seconds, 90 seconds, two minutes, three minutes or even longer without regard to the formation of bubbles on the surface of the implant. Moreover, Ellingsten et al do not say "no etching" they say "no significant etching" which one of ordinary skill in the art would reasonably interpret as "no macro-etching."

One of ordinary skill in the art desiring to practice the Ellingsen et al invention would have found it obvious as a matter of routine practice to have optimized the exposure time of the implants to the hydrofluoric acid to the time which gives the implants the best osteointegration results. The best osteointegration results inherently occur wherein the HF causes a minor amount of micro etching with pores having diameter of less than 1 micron and depth of less than half a micron. Such routine obvious optimization would have been particularly obvious in view of the prior art that teaches such small amounts of acid etching improve osteointegration of the implant. More particularly, Steinemann et al teach that micro roughness of 2 microns or less is preferred for titanium implants to improve osteointegration (note abstract) and that such roughness may be obtained with hydrofluoric acid (column 3, line 13) and Haruyuki et al teach titanium implants be etched such that they have pores with an average diameter of 1-10 microns and a depth of .5-5 microns (translation, page 4, column 1, lines 1-9) with an acid solution that contains hydrofluoric acid (translation, page 3, column 2, lines 22-24) in order to improve osteointegration. Accordingly, to have continued the Ellingsen HF acid treatment process until micropores of 1 micron were formed in order to further improve the osteointegration of the Ellingsen implant in view of the teachings by Steinemann et al and Haruyuki et al that such micro sized pores improve osteointegration and are readily formed by exposure to hydrofluoric acid would have been obvious to one of ordinary skill in the art.

In regard to the rms value of claim 29, such a value is inherent in such sized pores (note applicant's specification page 12, lines 1-50. In regard to the

macroroughness of claims 34 and 35, Steinemann et al teach that is desirable to sandblast the implant before prior to the acid etching which forms micropores (note column 3, lines 46-47). In regard to the "peaks having a peak width, at half the pore depth, of 15 to 150% of the pore diameter" limitation of claim 38, the measured characteristic appears to be an inherent result of the acid etching process. Applicant discloses no steps other than the acid etching to achieve such a physical characteristic.

#### **Action Made Final**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for



published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (571) 273-8300. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Cris Rodriguez, can be reached at (571) 272-4964.

R.Lewis  
February 11, 2010

/Ralph A. Lewis/  
Primary Examiner, Art Unit 3732